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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/447,227	11/22/1999	MARK C. SHULTS	MARKWELL-040	3546

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EXAMINER

NASSER, ROBERT L

ART UNIT	PAPER NUMBER
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3736

DATE MAILED: 07/09/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/447,227

Applicant(s)

SHULTS ET AL.

Examiner

Robert L. Nasser

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 18 April 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 5,21,22,24 and 28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 2,21,24 and 28-55 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

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Claims 21, 22, 24, and 28-55 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. All of the claims recite that the second domain is resistant to cellular attachment. As near as the examiner can tell, the second domain corresponds to the bioprotective membrane in the specification. Applicant does not disclose that the bioprotective layer is resistant to cellular attachment. Since this is a new limitation, it constitutes new matter. In addition, the claims now read that the second domain is impermeable to cells and cell processes. Applicant has disclosed that the bioprotective layer is substantially impermeable to microphages, but makes no mention of cells or cell processes. Indeed, if it were impermeable to cells and cell process, glucose could not reach the sensor and the device would not function. Again, since this is a new limitation, it constitutes new matter. Clarification is required.

Claims 21, 22, 24, and 28-55 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. All of the independent claims recite that the first domain is distal to the implantable device and that the sensing membrane is proximal to the device, . However, the first domain and the sensing membrane are defined as being part of the implantable device. It is unclear how a part of something can be distal to itself. Clarification is required

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The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 21, 22, 24, 28, 44, 45, 50, and 51 are rejected under 35 U.S.C. 103(a) as being obvious over Schulman et al in view of Picha. Schulman shows a device having a housing (see figure 6, for example) and a sensor where the device has a sensing membrane 24 having containing an enzyme, i.e. glucose oxidase, 34, where the sensing membrane is distally located with respect to a electrolytic phase 22, which is distal to a sensor 12, 14, 16, and 18. In addition, Schulman has a layer 38, which is resistant to cellular attachment and impermeable to some cells and cell processes. It does not have the first domain, recited in the claims. However, Picha teaches that providing an outer layer 14 to promote tissue ingrowth, i.e. an angiogenic layer, extends the useable life of a sensor. Hence, it would have been obvious to modify Schulman to use such an outer layer, to extend its useable life. The examiner notes that Schulman does not specifically say how long it can function inside the body. However, it is the examiner's position that the use of the outer layer of Picha allows it to be used as long as the time periods claimed.

Claims 29-33, 38-39, 41-43, 46-49, and 52-55 are rejected under 35 U.S.C. 103(a) as being obvious of Schulman et al in view of Picha and Ward et al. The combination of Schulman et al and Picha produces a device mounted on a catheter

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connected to the exterior of the patient via a wire. Ward et al teaches an equivalent glucose sensing method where the device is wholly implanted and the readings are transmitted out of the patient. Hence, it would have been obvious to modify the Schulman/Picha combination to use such transmission system, as it is merely the substitution of one known equivalent data reporting method for another. With respect to claim 31, the examiner notes that the sensor of Picha has a sensor tip interface and that the shape of Schulman is not limited to any particular shape. Hence, it would have been obvious to modify Schulman to use the shape of the Picha device, as it is merely the substitution of one known equivalent sensor shape for another.

Claim 34-37 and 40 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Applicant's arguments filed 4/18/2003 have been fully considered but they are deemed moot in view of the new grounds of rejection.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not

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mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert L. Nasser whose telephone number is (703) 308-3251. The examiner can normally be reached on MAXIFLEX.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (703) 308-3130. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-0758 for regular communications and (703) 308-0758 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

Robert L. Nasser
ROBERT L. NASSER
PRIMARY EXAMINER

Robert L. Nasser
Primary Examiner
Art Unit 3736

RLN
June 29, 2003